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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,466	04/16/2004	William H. Andrews	SIER-022CON	1298
24353	7590	04/10/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			NOBLE, MARCIA STEPHENS	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/826,466	Applicant(s) ANDREWS ET AL.	
	Examiner Marcia S. Noble	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46, 48, 49, and 53-61 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 46, 48, 49, and 53-61 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. In a response to the Non-Final Office Action, filed 1/27/2006, claims 1-45, 47, and 50-52 are withdrawn from consideration. Claims 46, 48, and 49 are under consideration. Claims 46 has been amended and claims 53-61 have been added.

Priority

2. Appendix A and previously filed amendment to the specification which amended the first paragraph of the specification to include the priority document is acknowledged and objection is withdrawn.

Specification

3. The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

Page 34, sec [96], par 2, last line: Sequence that required a SEQ ID NO has been amended and is now in compliance. Objection is withdrawn.

Claim Objections

4. Claim 46 was objected to because of the following informalities:

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"A method of determining whether an agent that inhibits GC-Box 5 repression of TERT transcription" suggests the "agent" has another primary function in the instant application other than inhibiting GC-Box 5 repression of TERT transcription.

Applicant has amended the claim appropriately and therefore the objection is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 46, 48, and 49 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 6-16 of copending Application No. 11/198,933. Although the conflicting claims are not identical,

they are not patentably distinct from each other because the breath of the claims from both applications encompass the same embodiments.

Willingness of Applicant to submit a Terminal Disclaimer pending allowance of claims 1-4 and 6-16 of the copending application, 11/198933, before the allowance of claims 46, 48, and 49 of the instant application to overcome an obvious-type double patenting rejection is acknowledged. However a rejection cannot be held in abeyance and the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 46, 48, 49 stand rejected and newly added claims 53-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant disagrees that the instant specification is not enabling on the grounds that (1) levels and type of experimentation by an artisan be known to one of ordinary skill in the art and would not be considered undue, and (2) the mechanism of action of

an agent that inhibits repression through the GC-Box-5 element would be not a limitation in the claims and therefore its mechanism is irrelevant.

These arguments have not been found persuasive for the following reasons:

To address the relevance of the mechanism of action of repression of the CG-Box-5 repressive element, examiner refers to an argument previously stated in the Non-Final Office Action. "Treating cells with an agent or small molecule that then coincides with increased TERT transcriptional activity does not necessarily mean that the inhibition of repression has occurred via the GC-Box5 element." In other words, the art that does describe the GC-Box 5 element suggests that it is a complicated system and that there are other factors that may be mask, attenuating, or mimic the effects of the GC-Box 5 repressive element. "

"Another repressor element may be function solely or in conjunction with GC-Box 5. Other repressor elements, such as WNT1 and Mad, have been disclosed as having repressive function in the hTERT promoter (Oh et al. J Biol Chem 274(52): 37473-37478, 1999, see abstract; Oh et al. Oncogene 19:1485-1490, 2000; see abstract)." (p. 11 last par). "Given little is known about how the GC-Box 5 functions in the instant invention, it is possible that other cofactors and transcription factors are needed. Furthermore, the GC-Box 5 element may be functioning in a more complex manner than disclosed by the claimed invention. Horikawa et al. also discloses the their analogous repressive GC-Box also overlaps with another GC-Box element that binds Sp1/Sp3 complex (p. 18439, Figure 2a), therefore suggesting involvement of the Sp1/Sp3

complex in repression their hTERT promoter activity in conjunction to the repressive GC-Box element.” (p. 12, end of last par).

Therefore, since the mechanism and interplay is not known at present, it is possible that an artisan that is using/making the instant invention to identify an agent can not know for sure that the TERT inhibition is due to the inhibition of the GC-Box 5 repressive element or a factor that is mimicking the effect of the GC-Box 5 repressive element. The specification does not provide enough guidance to determine if another system may work in tandem or mimic the repressive element and therefore an artisan would not know how to promote optimize this potential outcome. Therefore, the instant invention is not enabled.

While it may not be necessary to know all of the factors affecting the GC-Box 5 repressive mechanism in the claimed invention, a clear interpretation or nexus between the observation and effects is required. In the instant case, one can not rule out that other elements or factors other than the inhibition of the GC-Box 5 repressive element is resulting in the TERT promoter transcriptional activity. For example, the TERT promoter transcriptional activity may be due to the loss of inhibition by WNT1 or Mad, which have been described as having repressive function on the TERT promoter (Oh et al. J Biol Chem 274(52): 37473-37478, 1999, see abstract; Oh et al. Oncogene 19:1485-1490, 2000; see abstract).

While the methodology to add unknowns to a culture and observe an effect are simple, without a clear indication of what the observations mean, additional research on the system itself used in the assay would be required. This level of experimentation

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goes beyond standard optimization procedures and therefore it would be considered undue experimentation.

Claims 53-61 have been added, however, these claims only provide new limitations without providing any clarity to the interpretation of the method. The added claims specify the cells of the expression system as lacking telomerase expression or being MRC5 cells, the reporter be a luciferase or SEAP, the identified agent be a biomolecule, and the expression system be in a vector. The new claims do not clarify the relationship between the test agent and its ability to specifically inhibit GC-Box 5 repression of the TERT promoter and not induce TERT promoter by an alternative mechanism. Given that the new claims do not further clarify the interpretation or a nexus between the observation and effect, they do not overcome the previously described enablement issues and therefore the new claims are not enabled and are rejected under the enablement issues.

7. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marcia S. Noble

Joe Winters
AU 1632